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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/779,460	01/07/1997	OSCAR JOHANNES MARIA GODDIJN	U-011098-6	5897

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NEW YORK, NY 10023

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

35

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 08/779,460	Applicant(s) Goddijn et al
Examiner FOX	Group Art Unit 1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/17/03.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 25, 35-69 is/are pending in the application.
- ☐ Of the above claim(s) 37-38, 42, 51-55, 57-58, 63-64 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 25, 35, 36, 39-41, 43-50, 56, 58-62, 65-67, 69 is/are rejected.
- ☒ Claim(s) 68 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Acti n Summary

Art Unit: 1638

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendments of 17 January 2003 have obviated the indefiniteness rejections of record. The Ponstein declaration of 17 January 2003 has resulted in the modification of the enablement rejection, to the extent that non-exemplified chemical trehalase inhibitors are now considered enabled.

Claims 25, 35-36, 39-41, 43-50, 56, 59-62 and 65 remain, and new claims 66-67 and 69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for producing trehalose in plants transformed with a bacterial or fungal gene encoding trehalose phosphate synthase wherein the plants are treated with a chemical trehalase inhibitor, does not reasonably provide enablement for claims broadly drawn to plants which naturally produce trehalose or chemical treatment thereof, or the use of any other transgene encoding any other gene product. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action on pages 3-6.

Claims 25, 35-36, 39-41, 43-50, 56, 59-62 and 65 remain, and new claims 66-67 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last Office action on pages 6-7.

Art Unit: 1638

The claims remain free of the prior art, as stated in the last Office action.

Claim 68 (newly submitted) is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicants' arguments filed 17 January 2003, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection is improper, given the drafting of claims 35 and 63 in Jepson format, so that their preambles recite that which is known in the art; the lack of a requirement to teach what is well known in the art; and the demonstration of the isolation of tobacco and Jerusalem artichoke bipartite trehalose phosphate synthase genes.

The Examiner notes that most of the claims are not in Jepson format. Furthermore, the Examiner maintains that the Jepson format, while possibly constituting an admission of what Applicants believed was known in the prior art, does not relieve Applicants of demonstrating the enablement of their claims. Applicants have admitted that very few plants synthesize trehalose naturally. Those that do synthesize trehalose naturally are drought-resistant plants with wax-coated leaves, so that the efficacy of chemical treatment thereof is unclear. Furthermore, although plant transformation with a bacterial or fungal trehalose synthase phosphate gene was known in the art, other methods of obtaining a trehalose-synthesizing plant including the utilization of any other gene from any other source, were not known. Thus, the scope of the claims, including the

Art Unit: 1638

preamble of Jepson claims, must bear a reasonable correlation with what is enabled by the specification.

Regarding the alleged isolation of plant genes, the Examiner maintains that Applicants conclude that the putatively isolated genes encoded trehalose phosphate synthase, based upon homology analysis of the putatively encoded protein. However, Applicants do not disclose the degree of homology. In addition, it is well known in the art that estimations of gene function based solely on sequence homology are often erroneous.

Applicants urge that the written description rejection is improper, given the Jepson format of the claims and the disclosure of plant genes. The Examiner maintains that the Jepson format does not relieve Applicants of the requirement to provide an adequate written description of the claimed genus of sequences under 35 USC 112, first paragraph. With regard to the putative plant genes, the Examiner maintains that the function of the protein encoded by the putative genes was not confirmed, as discussed above. Furthermore, no structural features, such as sequence of the entire coding region, were disclosed for either putative plant gene. Since the actual function of the encoded protein was not demonstrated, there could be no demonstrated correlation between structural and functional features, as required to satisfy the written description requirement. See Revised Written Description Guidelines, Federal Register, Vol. 66, No. 4, Friday January 5, 2001, pages 1099-1111 and MPEP Section 2163.

Art Unit: 1638

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 6, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

